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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,247	01/14/2002	Adolfo Goren	P 0280702	1041
23873	7590	01/07/2004	EXAMINER	
ROBERT W STROZIER, P.L.L.C			COE, SUSAN D	
PO BOX 429			ART UNIT	
BELLAIRE, TX 77402-0429			PAPER NUMBER	

1654

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/076,247

Applicant(s)

GOREN ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.  
4a) Of the above claim(s) 1-7 and 14-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Q11402. 6) ☐ Other:

### DETAILED ACTION

1. Claims 1-38 are currently pending.

#### *Election/Restrictions*

2. Applicant's election of Group II, claims 8-13 and rhinovirus for species A in the paper submitted December 8, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 1-7 and 14-38 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper submitted December 8, 2003.
4. Claims 8-13 are examined on the merits solely in regards to the elected species of rhinovirus.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using *Allium cepa*, *A. ampeloprasum*, *A. fistulosa*, and *A. schoenoprasum* to treat rhinovirus infection, does not reasonably provide enablement for preventing rhinovirus infection. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are drawn to preventing rhinovirus infection of a patient using extracts from *A. cepa*, *A. ampeloprasum*, *A. fistulosa*, and *A. schoenoprasum*; however, the specification does not provide any examples that these extracts are able to prevent infection by this virus. The use of “prevention” requires that the claimed method of prevention work in each and every instance of the disease. It is well known in the art that viruses are able to enter a patient and potentially infect the patient through a variety of routes. Applicant has not shown that the extracts are able to prevent the virus from entering the patient and has not shown that the extracts are able to prevent infection if the virus does enter the patient. Thus, applicant has not shown that the extracts would be capable of preventing infection by a rhinovirus. Since applicant has not provided support for prevention, a person of ordinary skill in the art would be forced to experiment unduly to determine if the claimed extracts are able to prevent infection by rhinovirus in each and every instance of potential rhinovirus infection. Therefore, the claims are not considered to be enabled for “prevention” of rhinoviral infection.

6. Claims 8-10 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating rhinoviral infection with *A. cepa*, *A.*

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ampeloprasum, *A. fistulosa*, and *A. schoenoprasum*, does not reasonably provide enablement for using other *Allium* species to treat rhinoviral infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 8-10 and 13 are drawn to using any type of *Allium* species to treat rhinoviral infection. However, applicant's specification only discusses the use of *A. cepa*, *A. ampeloprasum*, *A. fistulosa*, and *A. schoenoprasum* to treat rhinoviral infection. There are dozens of *Allium* species that are not discussed by applicant. It is well known in the art that different species of the same genera do not necessarily have the same pharmaceutical properties. Thus, a person of ordinary skill in the art would be forced to test each and every other species of *Allium* in order to determine if applicant's invention functions are claimed. This is potentially a large number of experiments that the artisan would have to perform to ascertain if applicant's invention does work in the manner claimed. Therefore, due to the burden of experimentation, applicant's claims are not considered to be enabled for using every species of *Allium* to treat rhinoviral infection.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994).

Applicant's claims are drawn to treating rhinoviral infection using *A. cepa*, *A. ampeloprasum*, *A. fistulosa*, or *A. schoenoprasum*. The paragraph spanning pages 2 and 3 of applicant's specification defines the common names of *A. cepa* as onion, *A. ampeloprasum* as leek, *A. fistulosa* as scallion, and *A. schoenoprasum* as chives. To create the extracts the plants are dehydrated and processed to a particle size of 1 to 1400 microns. The extracts are administered orally. Rhinoviruses cause the common cold.

CN '152 teaches a method of curing the common cold using an onion product. The product is administered orally in a variety of forms. While the reference does specifically teach that the onion can be powdered, it does not specifically teach that the powder particles have the size claimed by applicant. Applicant claims a wide range of sizes for the particles. Included in this size range is a typical size for a particle of a powder. Thus, it seems very likely that the onion powder in the reference is of a size that would fall within applicant's claimed range. Since this is not explicitly disclosed, the reference does not clearly anticipate applicant's claims. However, the size of a powder for use in a pharmaceutical is clearly a result effect parameter that a person of ordinary skill in the art would routinely optimize. An artisan would be motivated to

modify the onion powder of the reference to produce a product with the best characteristics for administration to treat the rhinovirus that causes the common cold.

8. Claims 8-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1161840 A (1997).

CN '152 teaches a method of curing the common cold using product that contains scallion. The product is administered orally in a variety of forms. While the reference does specifically teach that the scallion containing product can be powdered, it does not specifically teach that the powder particles have the size claimed by applicant. Applicant claims a wide range of sizes for the particles. Included in this size range is a typical size for a particle of a powder. Thus, it seems very likely that the scallion powder in the reference is of a size that would fall within applicant's claimed range. Since this is not explicitly disclosed, the reference does not clearly anticipate applicant's claims. However, the size of a powder for use in a pharmaceutical is clearly a result effect parameter that a person of ordinary skill in the art would routinely optimize. An artisan would be motivated to modify the scallion powder of the reference to produce a product with the best characteristics for administration to treat the rhinovirus that causes the common cold.

9. Claims 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN '152 in view of US Pat. No. 5,705,152 (Plummer).

As discussed above, CN '152 teaches treating rhinovirus infection using an onion powder. However, the reference does not teach using chives and leeks to treat rhinovirus infection. Plummer teaches creating a plant extract from Allium species. The extract is created by drying Allium plants and crushing them into a powder (see paragraph spanning columns 2

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and 3). The extract has antiviral properties (see column 3, lines 46-48). The Allium species that can be used include onion, leek, and chives (see column 2, lines 53-57). Thus, this reference shows that it was known in the art at the time of the invention that powders from leek and chives have similar if not equivalent pharmaceutical and antiviral properties to onion powder. Based on this teaching of equivalence by Plummer, a person of ordinary skill in the art would reasonably expect that scallion and leek powders would also function to treat rhinovirus as taught by CN '152. Therefore, based on this reasonably expectation of success, a person of ordinary skill in the art would have been motivated to use leek and chives powders to treat rhinovirus infection.

While both references specifically teach that the Allium products can be powdered, they do not specifically teach that the powder particles have the size claimed by applicant. Applicant claims a wide range of sizes for the particles. Included in this size range is a typical size for a particle of a powder. Thus, it seems very likely that the Allium powders in the references would be of a size that would fall within applicant's claimed range; but, this is not explicitly disclosed in either reference. However, the size of a powder for use in a pharmaceutical is clearly a result effect parameter that a person of ordinary skill in the art would routinely optimize. An artisan would be motivated to modify the Allium powders of the references to produce a product with the best characteristics for administration to treat the rhinovirus that causes the common cold.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Please note that on January 20, 2003, these contact phone numbers will change. Examiner Coc's new phone number will be (571) 272-0963. Supervisory Examiner Brumback's new phone number will be (571) 272-0961. However, the fax phone number will remain (703) 872-9306.

  
Susan Coc, Examiner  
December 29, 2003